K082314

OCT 28 2008

# 510(k) SUMMARY
# of
# SAFETY and EFFECTIVENESS

## A. General Information

| | | |
|---|---|---|
| 1. | *Submitter's Name:* | OTTO BOCK Health Care, LP |
| 2. | *Address:* | Two Carlson Parkway North, Suite 100<br>Minneapolis, Minnesota USA 55447-4467 |
| 3. | *Telephone:* | 651-773-0002 |
| 4. | *Contact Person:* | William (Bill) Jackson |
| 5. | *Date Prepared:* | June 28, 2008 |
| 6. | *Registration Number:* | 2182293 |

## B. Device

| | | |
|---|---|---|
| 1. | *Name:* | BRAVOracer |
| 2. | *Trade Name:* | BRAVOracer |
| 3. | *Common Name:* | Manual Wheelchair |
| 4. | *Classification Name:* | Manual Wheelchair |
| 5. | *Product Code:* | IOR |
| 6. | *Class:* | I |
| 7. | *Regulation Number:* | 890.3850 |

## C. Identification of Legally Marketed Devices

1. *Name:* Start Junior
2. *K Number:* K073512
3. *Date Cleared:* January 14, 2008

## D. Description of the Device

The BRAVOracer is a lightweight, adaptive, and multifunctional wheelchair.

It was designed for children who are unable to walk or who have a walking impediment. This wheelchair can be moved either by the patient him/herself or by another person.

The BRAVOracer is a rigid frame of aluminum.Seat height is front and rear adjustable, with various widths and heights. It has a width of 47-66 cm. The seat material is nylon upholstery. All backs are adjustable and all armrests are removable. It has a swing-away footrest with a weight capacity of 60 kg or approximately 132 pounds.

Each wheelchair has the following accessories:

- Anti-Tipper
- Transport Wheels
- Crutch Holder
- Clothing Protector or Side Panels
- Drum Brakes
- Wheel Lock
- Tray
- Lap Belt
- Aluminum Footrest
- Elevating Footrest
- Folding Back
- Spoke Protectors
- 20-24" Rear Wheels

## E. Intended Use Statement

The BRAVOracer is a lightweight, rigid, high strength aluminum wheelchair for everyday use. This wheelchair provides mobility to physically challenged children. This wheelchair can be moved by the user propelling the hand rims, which are attached to the rear (drive) wheels. This wheelchair can also be pushed by an assistant grasping the pushbar attached to the back rest.

## F. Technological Characteristics Summary

The BRAVOracer is substantially equivalent to the Start Junior, cleared on January 14, 2008 as K073512.

The wheelchair is an aluminum frame, rigid, manual, folding wheelchair for everyday use with an adjustable seat, removable armrests, and adjustable back heights for users of approximately 60kg or 132 lbs.

The Start Junior was tested by Berlin Cert to the following standards:

- EN 12182
- EN 12183
- EN/ISO 10993-5
- ISO 7176-1
- ISO 7176-3
- ISO 7176-5
- ISO 7176-7
- ISO 7176-8
- ISO 7176-16
- ANSI/RESNA 7176-19

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 8 2008

Otto Bock Health Care, LP
% Mr. William Jackson
2247 Jennifer Lane
Saint Paul, Minnesota 55109

Re: K082314
Trade/Device Name: BRAVOracer Pediatric Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair.
Regulatory Class: Class I
Product Code: IOR
Dated: June 28, 2008
Received: August 28, 2008

Dear Mr. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use**

**510(k) Number** (if known): *To be determined*

**Device Name:** BRAVOracer Pediatric Manual Wheelchair

**Indications for Use:**

- Children who are unable to walk or who have a walking impediment.

Prescription Use ___ AND/OR Over-The-Counter Use _X_
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K082314